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10  
11 IN THE UNITED STATES DISTRICT COURT  
12 FOR THE NORTHERN DISTRICT OF CALIFORNIA  
13 (SAN FRANCISCO DIVISION)

CRB

14 IN RE: BEXTRA AND CELEBREX  
15 MARKETING SALES PRACTICES AND  
16 PRODUCT LIABILITY LITIGATION

MDL No. 1699

CV 08 0977

17 OLIVE BEEBE (OR), JOHN BYRD(MS), and  
18 EDDIE LOU TERRELL BLACK (MT)

Case No. \_\_\_\_\_

19 Plaintiffs,

CIVIL COMPLAINT

JURY TRIAL DEMANDED

20 v.

21 PFIZER, INC., PHARMACIA  
22 CORPORATION, G.D. SEARLE LLC, (FKA  
23 G.D. SEARLE & CO.), and MONSANTO  
24 COMPANY,

25 Defendants.

26 Plaintiffs, Olive Beebe, John Byrd and Eddie Lou Terrell Black by and through their  
27 counsel, bring this action against Defendants PFIZER, INC., PHARMACIA CORP.,  
28 MONSANTO COMPANY, and G.D. SEARLE LLC. (hereinafter collectively "Defendants") and  
allege as follows:

I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale,

COMPLAINT

1 testing, marketing, advertising, promotion, and/or distribution of the unsafe medication  
2 Celecoxib, trade name CELEBREX® (“CELEBREX”).

3 2. Plaintiff, Olive Beebe, was at all relevant times adult resident citizen of the State  
4 of Oregon, County of Washington. Plaintiff was prescribed and began taking CELEBREX for the  
5 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe  
6 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious  
7 cardiovascular injuries or heart attacks on or about February 18, 2008, which has caused and will  
8 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

9 3. Plaintiff, John Byrd, was at all relevant times adult resident citizen of the State of  
10 Mississippi, County of Orleans. Plaintiff was prescribed and began taking CELEBREX for the  
11 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe  
12 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious  
13 cardiovascular injuries or heart attacks on or about November 7, 2003, which has caused and will  
14 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

15 4. Plaintiff, Eddie Lou Terrell Black, was at all relevant times adult resident citizen  
16 of the State of Montana, County of Gallatin. Plaintiff was prescribed and began taking  
17 CELEBREX for the treatment of pain. As a direct and proximate result of using CELEBREX,  
18 Plaintiff suffered severe cardiovascular injuries while taking CELEBREX, including, but not  
19 limited to, serious cardiovascular injury or heart attack on or about January 14, 2003, which has  
20 caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious  
21 injury or death.

22 5. Defendant Pfizer Inc. (“Pfizer”) is a Delaware corporation with its principal place  
23 of business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly  
24 \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the  
25 business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and  
26 selling the drug Celecoxib, under the trade name CELEBREX in California and nationwide.

27 6. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. (“Searle”) is  
28 a Delaware corporation with its principal place of business in Illinois. At all relevant times,  
Searle has been engaged in the business of marketing and selling CELEBREX nationwide and in

1 California. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged  
2 within this Complaint.

3 7. Defendant Monsanto Company ("Monsanto") was the parent corporation of Searle  
4 and is a Delaware corporation. At all times relevant hereto, Monsanto, through its subsidiary  
5 companies, was in the business of manufacturing, marketing, selling and distributing the  
6 pharmaceutical product CELEBREX nationwide.

7  
8 8. Defendant Pharmacia Corporation ("Pharmacia ") is a Delaware corporation with  
9 its principal place of business in New Jersey. At all relevant times, Pharmacia, and its  
10 predecessors in interest have been engaged in the business of designing, testing, manufacturing,  
11 packaging, marketing, distributing, promoting, and selling CELEBREX nationwide and in  
12 California.

## 13 II. JURISDICTION AND VENUE

14  
15 9. This is an action for damages, which exceeds seventy-five thousand dollars  
16 (\$75,000.00).

17 10. There is complete diversity of citizenship between the Plaintiffs and Defendants.  
18 This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332  
19 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there  
20 is complete diversity of citizenship between Plaintiffs and Defendants.

21 11. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A.  
22 § 1391. Defendants marketed, advertised and distributed the dangerous product in the district,  
23 thereby receiving substantial financial benefit and profits the dangerous product in this district,  
24 and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

25 12. At all relevant times herein, Defendants were in the business of designing,  
26 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and  
27 selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed,  
28 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce  
the aforementioned prescription drug. Defendants do substantial business Nationwide and within

1 this Federal Judicial District, advertise in this district, receive substantial compensation and  
2 profits from sales of CELEBREX in this District, and made material omissions and  
3 misrepresentations and breaches of warranties in this District so as to subject them to *in personam*  
4 jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the  
5 agent for each of the other defendants, or those defendant's predecessors in interest.

### 6 **III. INTERDISTRICT ASSIGNMENT**

7 13. Assignment to the San Francisco Division is proper as this action is related to *In*  
8 *Re: Celebrex and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the  
9 Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,  
10 2005. (See also, MDL-1699 Pretrial Order No. 2)

### 11 **IV. FACTUAL BACKGROUND**

#### 12 **A. Facts Regarding All Plaintiffs**

13 14. Plaintiffs and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries  
14 unaware - and could not have reasonably known or have learned through reasonable diligence -  
15 that such injury directly resulted from Defendants' negligent and otherwise culpable acts,  
16 omissions, and misrepresentations or from Plaintiffs' ingestion of CELEBREX.

17  
18 15. Plaintiffs used CELEBREX in a proper and reasonably foreseeable manner and  
19 used it in a condition that was substantially the same as the condition in which it was  
20 manufactured and sold.

21 16. Plaintiffs would not have used CELEBREX had Defendants properly disclosed the  
22 risks associated with the drug.

#### 23 **B. Facts Regarding CELEBREX: Science and other Cox-2 Inhibitors**

24  
25 17. CELEBREX is one of a class of pain medications called non-steroidal anti-  
26 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade  
27 name Advil) are examples of well-known NSAIDs.  
28



1           18.     NSAIDs reduce pain by blocking the body's production of pain transmission  
2 enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and  
3 COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

4           19.     In addition to decreasing inflammation, the prostaglandins that are supported by  
5 COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall  
6 from the hydrochloric acid present in the stomach. It is generally accepted in the medical  
7 community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is  
8 hampered and as a result, can cause harmful gastrointestinal side effects, including stomach  
9 ulceration and bleeding.

10           19.     Prosagalin I2 is the predominant cyclooxygenase product in endothelium,  
11 inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing  
12 the proliferation of vascular smooth muscle. Whereas older NSAIDs inhibit Thromboxane A2  
13 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2  
14 is a potent platelet aggregator and vasoconstrictor which is synthesized by platelets. Therefore,  
15 while the older NSAIDs suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors  
16 support it.

17           20.     Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by  
18 inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional  
19 NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood  
20 clots, rather they actually reduce the risk of clots and help protect heart function.

21           21.     Defendants and other pharmaceutical companies set out to remedy these ulcer and  
22 bleeding problems suffered by some NSAID users by developing "selective" inhibitors that  
23 would block only COX-2 production, thus (supposedly) allowing the proper maintenance of  
24 gastric tissue while still reducing inflammation.

1           22. In making this decision, Defendants and their predecessors in interest either  
2 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2  
3 inhibition lowers prostacyclin levels and causes thromboxane A<sub>2</sub> to be uninhibited, causing blood  
4 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,  
5 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

7           23. Pfizer launched CELEBREX, the first of the three major COX-2 inhibitor drugs, in  
8 January 1999 and initiated a massive marketing campaign to convince doctors and consumers of  
9 the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May, 1999,  
10 Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

12           24. Seeking increased market share in this extremely lucrative market, Defendants,  
13 and their predecessors in interest, also sought approval of a “second generation” selective COX-2  
14 inhibitor and filed for FDA approval of Celecoxib (Celebrex) on January 16, 2001 for the  
15 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief  
16 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

18  
19           C. Facts Regarding CELEBREX’S Safety and Defendants’ Knowledge Thereof

20           25. The potential for cardiovascular risk of selective COX-2 inhibitors was known to  
21 Defendants long before the market launch. By 1997, and prior to the submission of the New  
22 Drug Application (the “NDA”) for CELEBREX, Defendants was aware that, by inhibiting COX-  
23 2, CELEBREX altered the homeostatic balance between prostacyclin synthesis and thromboxane  
24 and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those  
25 who ingested it. *See Topol, E.J., et al., Risk of Cardiovascular Events Associated with Selective*  
26 *Cox-2 Inhibitors, JAMA, August 22, 2001 at 954.*  
27  
28

1           26. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania,  
2 reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004,  
3 that it was known as early as 1999 that selective COX-2 inhibitors, such as CELEBREX,  
4 suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation  
5 in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.  
6

7           27. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and  
8 basic research on this type of selective inhibitor which had been widely conducted, Defendants  
9 knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed  
10 serious cardiovascular risks for anyone who took them, and presented a specific additional threat  
11 to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective  
12 COX-2 inhibitors, including CELEBREX, decrease blood levels of a prostacyclin. When those  
13 levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and  
14 stroke.  
15

16  
17           28. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing  
18 new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action  
19 to protect the health and welfare of patients, but instead, continued to promote the drug for sale  
20 even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug  
21 Advisory Committee meetings.  
22

23           **1. CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

24           29. The defendants touted the CELEBREX Long-Term Arthritis Safety Study  
25 ("CLASS") as the primary evidence to support its theory that CELEBREX was safer for  
26 consumers that could not tolerate traditional NSAIDs in their gastrointestinal system. (CLASS  
27 data is found in NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000.  
28

1 CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D.  
2 (FDA Medical Officer) on September 20, 2000.)

3  
4 **2. CLASS**

5 30. The FDA Medical Officer Review of the CLASS data proves CELEBREX is no  
6 more efficacious than other traditional NSAIDS and is harmful to consumers. See generally,  
7 FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by G.D. Searle on  
8 June 12, 2000 ("FDA CLASS Review"). On April 7, 2005, the FDA issued an *Alert* noting only  
9 minimal information is available regarding CELEBREX: "The only available data from a long  
10 term comparison of CELEBREX to other NSAIDs came from the CLASS study...."

11  
12 31. Pfizer misrepresented the data in CLASS by using biased authors. According to  
13 the *Washington Post* the CLASS authors were either employees of Pharmacia, CELEBREX'S  
14 manufacturer, or paid consultants of the company. Pfizer needed a study to demonstrate that its  
15 Cox-2 inhibitor was safer for the stomach than older cheaper medications: CLASS was designed  
16 to be that study. Unfortunately, the results of the completed study revealed the truth –  
17 CELEBREX offered no gastrointestinal (GI) benefit. Instead of releasing the complete –12-  
18 month – results from CLASS, Pfizer had only the first six months of data published in the Journal  
19 of American Medicine. JAMA 2000;48:1455-1460.

20  
21 32. "After reviewing the full study, the FDA's arthritis advisory committee concluded  
22 that CELEBREX offers no proven safety advantage over the two older drugs in reducing the risk  
23 of ulcer complications, said FDA spokesman Susan Cruzan." *Washington Post*, August 5, 2001.  
24 According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any  
25 statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with  
26 regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal  
27 Adverse Events) at any point in the trial although there were trends that favored celecoxib" (FDA  
28



1 CLASS Review)

2 33. According to an August 5, 2001 article in the *Washington Post*, editors of the  
3 Journal of the American Medical Association (JAMA) and other medical experts, “were  
4 flabbergasted” when they realized they had been duped by only being provided with the first six  
5 months of CLASS data. The *Washington Post* reported JAMA editors as saying: “When all of the  
6 data were considered, most of CELEBREX’S apparent safety advantage disappeared.”

7 34. The “scientific double-cross” boosted sales. “[T]he JAMA article and editorial  
8 have likely contributed to CELEBREX’S huge sales. ‘When the JAMA article comes out and  
9 confirms the hype, that probably has more impact than our labeling does,’ said Robert J. Temple,  
10 director of medical policy at the FDA’s Center for Drug Evaluation and Research.” *Washington*  
11 *Post*, August 5, 2001.

12 35. “A total of 36 deaths occurred during the [CLASS] study or during post study  
13 follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . .  
14 Most deaths were cardiovascular in nature.” FDA CLASS Review, at 54. The increased number  
15 of adverse cardiovascular events in the CELEBREX group was not surprising as they were also  
16 revealed in the original New Drug Application (NDA) submitted for CELEBREX. “In the  
17 original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as  
18 compared to placebo treated patients. In the long term trial (Trial 024) that was included in the  
19 NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any  
20 does was cardiovascular.” FDA CLASS Review at 78.

21 36. Public Citizen, a public watchdog organization, reviewed the CLASS data in its  
22 entirety. A complete review reveals the combined anginal adverse events were 1.4% in celecoxib  
23 (CELEBREX) group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in  
24 the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

25 37. The CLASS data proves that Pfizer knew that its first generation Cox-2 inhibitor,  
26 CELEBREX, caused a disproportionately and statistically significantly high number of adverse  
27 cardiovascular events before it was introduced to the market in January 1999. According to  
28 Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the CV risk of

1 COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this  
2 placebo-controlled trial of CELEBREX.

3 **3. APC Trial**

4 38. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and  
5 safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the  
6 number of deaths from cardiovascular causes was significantly higher in the CELEBREX group  
7 when compared to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX  
8 400mg). Id. at 1075.

10 39. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and  
11 safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the  
12 number of deaths from cardiovascular causes was significantly higher in the CELEBREX group  
13 when compared to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX  
14 400mg). Id. at 1075.

16 40. The FDA Reported the APC data as follows<sup>1</sup>:

18  
19 In the National Cancer Institute's Adenoma Prevention with  
20 Celecoxib (APC) trial in patients at risk for recurrent colon polyps,  
21 a 2-3 fold increased risk of serious adverse CV events was seen for  
22 CELEBREX compared to placebo after a mean duration of  
23 treatment of 33 months. There appeared to be a dose response  
relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg  
twice daily and 3.4 CELEBREX 400 mg twice daily for the  
composite endpoint of death from CV causes, myocardial infarction  
(MI), or stroke.

24 41. The dosage noted in the study is important for two reasons: first, there appears to  
25 be an association between dosage and the increase in adverse cardiovascular events. See  
26 generally, at 1077. Second, most patients increase dosage. Pfizer knew patients were increasing  
27 their dosages as noted in CLASS: "Interestingly ... up to 70% of patients increased their dose for  
28

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<sup>1</sup> April 7, 2005 FDA Alert: [www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm](http://www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm).

celecoxib.” FDA CLASS Review at 74. Thus, Pfizer was aware of the dosage creep.

### 3. Other CELEBREX Trials

42. Several other CELEBREX trials also gave Defendants insight into the cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

43. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected “the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)”<sup>2</sup>. According to Dr. Sidney Wolfe, “The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo.”<sup>3</sup>

### 4. Cox-2 Studies: VIGOR and APPROVE

44. Pfizer also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, Pfizer had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROV).

#### a. VIGOR

45. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

46. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant

<sup>2</sup> *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe.

<sup>3</sup> *Id.*

1 discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure  
2 adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice  
3 the risk of naproxen and the results were considered statistically significant.

4 47. The VIGOR study comprised the most definitive scientific evidence ever obtained  
5 about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of  
6 medical research. It was a safety study with endpoints set in advance. As Merck stated many  
7 times, it was designed to provide definite proof of safety, convincing enough to silence the most  
8 skeptical critics. In medical terms, the VIGOR results raised the question of whether selective  
9 inhibition of Cox-2 was a monumental mistake from the start. While the NSAID risks to the GI  
10 system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the  
11 arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including  
12 Defendants, were aware of these results.

13 **b. APPROVE**

14 48. Anxious to put safety questions surrounding Vioxx to rest, Merck designed  
15 another large scale trial, Adenomatous Polyp Prevention (APPROVE), which was intended to test  
16 the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular  
17 safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of  
18 the APPROVE data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and  
19 "doubled the risk of MI (myocardial infarction a/k/a heart attack)<sup>4</sup>. *Public Citizen*, January 24,  
20 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx,  
21 Pfizer never paused to re-evaluating the CELEBREX data and studies.

22 49. The scientific data available during and after CELEBREX'S approval process  
23 made clear to Defendants that their formulation of CELEBREX would cause a higher risk of  
24 blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to  
25 the need to do additional and adequate safety studies.

26 \_\_\_\_\_  
27 <sup>4</sup> Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVE trial did  
28 not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant  
increase in risk of heart attack was evident in as little as 4 months time.



1           50. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of*  
2 *Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing  
3 to humans "... it is mandatory to conduct a trial specifically assessing cardiovascular risk and  
4 benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established  
5 coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and  
6 have the highest risk of further cardiovascular events."

7           51. Dr. Topol was also the author on the study published in August 2001 in JAMA  
8 (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who  
9 used COX-2 inhibitors.

10          52. Based upon readily available scientific data, Defendants knew, or should have  
11 known, that their pre-approval testing of CELEBREX did not adequately represent the cross-  
12 section of individuals who were intended consumers and therefore, likely to take CELEBREX.  
13 Therefore, Defendants' testing and studies were grossly inadequate.

14          53. Had Defendants done adequate testing prior to approval and "market launch,"  
15 rather than the extremely short duration studies done on the small size patient base that was  
16 actually done the defendants' scientific data would have revealed significant increases in  
17 incidence of strokes and myocardial infarctions among the intended and targeted population of  
18 CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed  
19 serious side effects. Defendants should have taken appropriate measures to ensure that their  
20 defectively designed product would not be placed in the stream of commerce and/or should have  
21 provided full and proper warnings accurately and fully reflecting the scope and severity of  
22 symptoms of those side effects should have been made.

23          54. In fact, post-market approval data did reveal increased risks of clotting, stroke and  
24 myocardial infarction, but Defendants intentionally suppressed this information in order for them  
25 to gain significant profits from continued CELEBREX sales.  
26  
27  
28

1           55. Defendants' failure to conduct adequate testing and/or additional testing prior to  
2 "market launch" was based upon their desire to generate maximum financial gains for themselves  
3 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

4           56. At the time Defendants manufactured, advertising, and distributed CELEBREX to  
5 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding  
6 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants  
7 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but  
8 instead would purchase other cheaper and safer NSAIDs.

9           **D. Facts Regarding Defendants' Marketing and Sale of CELEBREX**

10          57. Such an ineffective and unreasonably dangerous drug could only be widely  
11 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the  
12 Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and  
13 misleading advertising, consumers, including the Plaintiff, would not have purchased  
14 CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

15          58. On January 10, 2005 the FDA issued Pfizer a written reprimand for its  
16 promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and  
17 2 Celebrex] variously: omit material facts ... and make misleading safety, unsubstantiated  
18 superiority, and unsubstantiated effectiveness claims." This was not the Defendants first offense  
19 related to its Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting:  
20 "DDMAC has reviewed these promotional pieces and has determined that they are false or  
21 misleading because they contain unsubstantiated comparative claims, misrepresentations of  
22 CELEBREX'S safety profile, and are lacking in fair balance." Ultimately, on April 8, 2005, the  
23 New York Times reported the results of an FDA advisory panel: "The February advisory panel  
24 voted overwhelmingly that the company should never again advertise the drug [CELEBREX]."

25          59. At all times relevant herein, Defendants engaged in a marketing campaign with the  
26 intent that consumers would perceive CELEBREX as a safer and better drug than its other  
27 NSAIDs and, therefore, purchase CELEBREX.

1           60. Defendants widely and successfully marketed CELEBREX throughout the United  
2 States by, among other things, conducting promotional campaigns that misrepresented the  
3 efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was  
4 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.  
5 Defendants made misrepresentations by means of media advertisements, and statements  
6 contained in sales literature provided to Plaintiff's prescribing physicians.

7           61. Despite knowledge of the dangers presented by CELEBREX, Defendants and  
8 Defendants' predecessors in interest, through their officers, directors and managing agents for the  
9 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy  
10 the known defects of Defendants' product, CELEBREX, and failed to warn the public, including  
11 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,  
12 CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with  
13 the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants'  
14 product, CELEBREX, knowing that persons would be exposed to serious potential danger, in  
15 order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and  
16 displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

17           62. In an elaborate and sophisticated manner, Defendants aggressively marketed  
18 CELEBREX directly to consumers and medical professionals (including physicians and leading  
19 medical scholars) in order to leverage pressure on third party payers, medical care organizations,  
20 and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced  
21 with the increased demand for the drug by consumers and health care professionals that resulted  
22 from Defendants' successful advertising and marketing blitz, third party payors were compelled  
23 to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted  
24 third party payors, physicians, and consumers, and was designed to convince them of both the  
25 therapeutic and economic value of CELEBREX.

26           63. Defendants represented that CELEBREX was similar to ibuprofen and naproxen  
27 but was superior because it lacked any of the common gastrointestinal adverse side effects  
28

1 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,  
2 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with  
3 long-term use. Defendants promoted CELEBREX as a safe and effective alternative that would  
4 not have the same deleterious and painful impact on the gut, but that would be just as effective, if  
5 not more so, for pain relief.

6 64. CELEBREX possessed dangerous and concealed or undisclosed side effects,  
7 including the increased risk of serious cardiovascular events, such as heart attacks, unstable  
8 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as  
9 strokes. In addition, CELEBREX was no more effective than traditional and less expensive  
10 NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and  
11 gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

12 65. Defendants knew of these risks before the U.S. Food and Drug Administration (the  
13 "FDA") approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed,  
14 omitted, and concealed these serious safety risks and denied inefficacy in its promotion,  
15 advertising, marketing, and sale of CELEBREX. Defendants' omission, suppression, and  
16 concealment of this important information enabled CELEBREX to be sold to, and purchased, or  
17 paid for by, the Consumers at a grossly inflated price.

18 66. Consequently, CELEBREX captured a large market share of anti-inflammatory  
19 drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded \$2  
20 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in  
21 the same family of drugs.

22 67. Because Defendants engaged in a promotional and marketing campaign that  
23 featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer  
24 drug than other drugs in its class, while uniformly failing to disclose the health risks of  
25 CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the  
26 cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed  
27 the truth about CELEBREX, Defendants would not and could not have reaped the billions of  
28



1 dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission,  
2 suppression, and obfuscation of the truth.

3 68. The Defendants intentionally, deliberately, knowingly, and actively concealed,  
4 omitted, suppressed, and obfuscated important and material information regarding the risks,  
5 dangers, defects, and disadvantages of CELEBREX from Plaintiff, the public, the medical  
6 community, and the regulators. This concealment and omission was deliberate, knowing, active,  
7 and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and  
8 prevented Plaintiff from obtaining all the material information that would be important to their  
9 decisions as reasonable persons to purchase, pay for, and/or use CELEBREX.

10 69. Defendants' systematic, active, knowing, deliberate, and uniform concealment,  
11 omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use  
12 CELEBREX; and caused Plaintiff's losses and damages as asserted herein.

13 70. Had Defendants done adequate testing prior to approval and "market launch," the  
14 defendants' scientific data would have revealed significant increases in stroke and myocardial  
15 infarction amongst the intended population of CELEBREX consumers. Adequate testing would  
16 have shown that CELEBREX possessed serious side effects. Defendants should have taken  
17 appropriate measures to ensure that their defectively designed product would not be placed in the  
18 stream of commerce and/or should have provided full and proper warnings accurately and fully  
19 reflecting the scope and severity of symptoms of those side effects should have been made.

20 71. In fact, post-market approval data did reveal increased risks of clotting, stroke and  
21 myocardial infarction, but Defendants intentionally suppressed this information in order for them  
22 to gain significant profits from continued CELEBREX sales.

23 72. Defendants' failure to conduct adequate testing and/or additional testing prior to  
24 "market launch" was based upon their desire to generate maximum financial gains for themselves  
25 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

26 73. At the time Defendants manufactured, advertising, and distributed CELEBREX to  
27 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding  
28

1 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants  
2 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but  
3 instead would purchase other cheaper and safer NSAID drugs.

4 **CLAIMS FOR RELIEF**

5 **FIRST CLAIM FOR RELIEF**

6 **Negligence**

7 74. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
8 fully set forth herein and further allege as follows.

9 75. Defendants owed Plaintiffs a duty to exercise reasonable care when designing,  
10 manufacturing, marketing, advertising, distributing, and selling CELEBREX. This duty included  
11 the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the stream of  
12 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side  
13 effects.  
14

15 76. At all relevant times to this action, Defendants owed a duty to properly warn  
16 Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical  
17 drug CELEBREX.

18 77. Defendants breached their duties by failing to exercise ordinary care in the  
19 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
20 marketing, promotion, advertising and selling of CELEBREX, including: failing to use due care  
21 in the preparation and development of CELEBREX to prevent the aforementioned risk of injuries  
22 to individuals when the drugs were ingested;

23 a. failing to use due care in the design of CELEBREX to prevent the aforementioned  
24 risk of injuries to individuals when the drugs were ingested;

25 b. failing to conduct adequate pre-clinical testing and research to determine the safety  
26 of CELEBREX;  
27  
28

1 c. failing to conduct adequate post-marketing surveillance and exposure studies to  
2 determine the safety of CELEBREX;

3  
4 d. failing to completely, accurately and in a timely fashion, disclose the results of the  
5 pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the  
6 medical community, and the FDA;

7  
8 e. failing to accompany CELEBREX with proper warnings regarding all possible  
9 adverse side effects associated with the use of CELEBREX;

10  
11 f. failing to use due care in the manufacture, inspection, and labeling of CELEBREX  
12 to prevent the aforementioned risk of injuries to individuals who used CELEBREX;

13  
14 g. failing to use due care in the promotion of CELEBREX to prevent the  
15 aforementioned risk of injuries to individuals when the drugs were ingested;

16  
17 h. failing to use due care in the sale and marketing of CELEBREX to prevent the  
18 aforementioned risk of injuries to individuals when the drugs were ingested;

19  
20 i. failing to use due care in the selling of CELEBREX to prevent the aforementioned  
21 risk of injuries to individuals when the drugs were ingested;

22  
23 j. failing to provide adequate and accurate training and information to the sales  
24 representatives who sold CELEBREX;

25  
26 k. failing to provide adequate and accurate training and information to healthcare  
27 providers for the appropriate use of CELEBREX; and

28 l. being otherwise reckless, careless and/or negligent.

1           79. Despite the fact that Defendants knew or should have known that CELEBREX  
2 caused unreasonable and dangerous side effects which many users would be unable to remedy by  
3 any means, Defendants continued to promote and market CELEBREX to consumers, including  
4 Plaintiffs, when safer and more effective methods of pain relief were available.  
5

6           80. Defendants were, or should have been, had they exercised reasonable care, in  
7 possession of evidence demonstrating that CELEBREX caused serious side effects. Nevertheless,  
8 they continued to market their products by providing false and misleading information with  
9 regard to the safety and efficacy of CELEBREX.  
10

11           81. Defendants knew or should have known that consumers such as Plaintiffs would  
12 foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.  
13

14           82. As a direct and proximate consequence of Defendants' acts, omissions, and  
15 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
16 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
17 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
18 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
19 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
20 preexisting conditions and activation of latent conditions, and other losses and damages.  
21  
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28



1 Plaintiffs also incurred direct medical losses and costs include care for hospitalization,  
2 physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss  
3 of wages.

4  
5 83. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
6 and deliberate disregard for the value of human life and the rights and safety of consumers,  
7 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
8 punish Defendants and deter them from similar conduct in the future.

9  
10 84. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
11 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
12 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

### 13 **SECOND CLAIM FOR RELIEF**

#### 14 **Strict Liability**

15 85. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
16 fully set forth herein and further allege as follows.

17 86. At all times relevant to this action, Defendants were suppliers of CELEBREX,  
18 placing the drug into the stream of commerce. CELEBREX was expected to and did reach  
19 Plaintiffs without substantial change in the condition in which it was manufactured and sold.

20 87. CELEBREX was unsafe for normal or reasonably anticipated use.

21 88. CELEBREX was defective in design or formulation because when it left the hands  
22 of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an  
23 ordinary consumer would expect. CELEBREX was also defective and unreasonably dangerous in  
24 that the foreseeable risk of injuries from CELEBREX exceeded the benefits associated with the  
25 design and/or formulation of the product.

26 89. Celebrex is unreasonably dangerous: a) in construction or composition; b) in  
27 design; c) because an adequate warning about the product was not provided; d) because it does  
28 not conform to an express warranty of the manufacturer about the product.

1           90. The characteristics of Celebrex that render it unreasonably dangerous under  
2 existed at the time the product left the control of the manufacturer or resulted from a  
3 reasonably anticipated alteration or modification of the product.

4           91. The CELEBREX manufactured and supplied by Defendants was also defective  
5 due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate  
6 reporting regarding the results of the clinical trials, testing and study. Defendants failed to  
7 perform adequate testing before exposing Plaintiffs to the medication, testing which would have  
8 shown that CELEBREX had the potential to cause serious side effects including strokes like that  
9 which affected Plaintiffs.

10          92. The CELEBREX manufactured and supplied by Defendants was defective due to  
11 inadequate post-marketing warnings or instructions because, after Defendants knew or should  
12 have known of the risk of injuries from CELEBREX, they failed to provide adequate warnings to  
13 the medical community and the consumers, to whom they were directly marketing and  
14 advertising CELEBREX; and, further, it continued to affirmatively promote CELEBREX as safe  
15 and effective.

16          93. CELEBREX was manufactured, distributed, tested, sold, marketed, advertised and  
17 promoted defectively by Defendants, and as a direct and proximate cause of Defendants'  
18 defective design of CELEBREX, Plaintiffs used CELEBREX rather than other safer and cheaper  
19 NSAIDs. As a result, Plaintiffs suffered the personal injuries described above.

20          94. Information given by Defendants to the medical community and to the consumers  
21 concerning the safety and efficacy of CELEBREX, especially the information contained in the  
22 advertising and promotional materials, did not accurately reflect the potential side effects of  
23 CELEBREX.

24          95. Had adequate warnings and instructions been provided, Plaintiffs would not have  
25 taken CELEBREX as they did, and would not have been at risk of the harmful side effects  
26 described herein.

27          96. Defendants acted with conscious and deliberate disregard of the foreseeable harm  
28 caused by CELEBREX.

          97. Plaintiffs could not, through the exercise of reasonable care, have discovered

1 CELEBREX's defects or perceived the dangers posed by the drug.

2 98. As a direct and proximate consequence of Defendants' acts, omissions, and  
3 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
4 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
5 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
6 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
7 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
8 preexisting conditions and activation of latent conditions, and other losses and damages.  
9 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
10 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

11 99. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
12 and deliberate disregard for the value of human life and the rights and safety of consumers,  
13 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
14 punish Defendants and deter them from similar conduct in the future.

15 100. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
16 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
17 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

### 18 **THIRD CLAIM FOR RELIEF**

#### 19 **Breach of Express Warranty**

20 101. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
21 fully set forth herein and further allege as follows.

22 102. Defendants expressly represented to Plaintiffs and other consumers and the  
23 medical community that CELEBREX was safe and fit for its intended purposes, that it was of  
24 merchantable quality, that it did not produce any dangerous side effects, particularly any  
25 unwarned-of side effects, and that it was adequately tested.

26 103. These warranties came in the form of:

27 a. Defendants' public written and verbal assurances of the safety and efficacy of  
28 CELEBREX;

b. Press releases, interviews and dissemination via the media of promotional

1 information, the sole purpose of which was to create an increased demand for CELEBREX,  
2 which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to  
3 the long-term ingestion of CELEBREX;

4 c. Verbal and written assurances made by Defendants regarding CELEBREX and  
5 downplaying the risk of injuries associated with the drug;

6 d. False and misleading written information, supplied by Defendants, and published  
7 in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing  
8 CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

9 c. advertisements.

10  
11 104. The documents referred to above were created by and at the direction of  
12 Defendants.

13 105. Defendants knew or had reason to know that CELEBREX did not conform to these  
14 express representations in that CELEBREX is neither as safe nor as effective as represented, and  
15 that CELEBREX produces serious adverse side effects.

16 106. CELEBREX did not and does not conform to Defendants' express representations  
17 because it is not safe, has numerous and serious side effects, including unwarned-of side effects,  
18 and causes severe and permanent injuries.

19 107. Plaintiffs, other consumers, and the medical community relied upon Defendants'  
20 express warranties.

21 108. As a direct and proximate consequence of Defendants' acts, omissions, and  
22 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
23 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
24 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
25 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
26 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
27 preexisting conditions and activation of latent conditions, and other losses and damages.  
28 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.



109. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

110. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

#### **FOURTH CLAIM FOR RELIEF**

##### **Breach of Implied Warranty**

111. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

112. Defendants manufactured, distributed, advertised, promoted, and sold CELEBREX.

113. At all relevant times, Defendants knew of the use for which CELEBREX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

114. Defendants were aware that consumers, including Plaintiffs, would use CELEBREX for treatment of pain and inflammation and for other purposes.

115. Plaintiffs and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe CELEBREX only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiffs, and the medical community, reasonably relied upon Defendants' implied warranty for CELEBREX.

116. CELEBREX reached consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

117. Defendants breached their implied warranty to consumers, including Plaintiffs; CELEBREX was not of merchantable quality or safe and fit for its intended use.

118. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.

1 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
2 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
3 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
4 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
5 preexisting conditions and activation of latent conditions, and other losses and damages.  
6 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
7 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

8 119. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
9 and deliberate disregard for the value of human life and the rights and safety of consumers,  
10 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
11 punish Defendants and deter them from similar conduct in the future.

12 120. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
13 compensatory damages and punitive and exemplary damages together with interest, the costs of  
14 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

#### 15 **FIFTH CLAIM FOR RELIEF**

##### 16 **Fraudulent Misrepresentation & Concealment**

17 121. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
18 fully set forth herein and further allege as follows.

19 122. Defendants' superior knowledge and expertise, their relationship of trust and  
20 confidence with doctors and the public, their specific knowledge regarding the risks and dangers  
21 of CELEBREX, and their intentional dissemination of promotional and marketing information  
22 about CELEBREX for the purpose of maximizing its sales, each gave rise to the affirmative duty  
23 to meaningfully disclose and provide all material information about CELEBREX's risks and  
24 harms to doctors and consumers.

25 123. Defendants made fraudulent affirmative misrepresentations with respect to  
26 CELEBREX in the following particulars:

27 a. Defendants represented through their labeling, advertising, marketing materials,  
28 detail persons, seminar presentations, publications, notice letters, and regulatory submissions that  
CELEBREX had been tested and found to be safe and effective for the treatment of pain and

1 inflammation; and

2 b. Defendants represented that CELEBREX was safer than other alternative  
3 medications.

4 124. Defendants made affirmative misrepresentations; and fraudulently, intentionally  
5 and/or recklessly concealed material adverse information regarding the safety and effectiveness of  
6 CELEBREX.

7 125. Defendants made these misrepresentations and actively concealed adverse  
8 information at a time when Defendants knew or had reason to know that CELEBREX had defects  
9 and was unreasonably dangerous and was not what Defendants had represented to the medical  
10 community, the FDA and the consuming public, including Plaintiffs.

11 126. Defendants omitted, suppressed and/or concealed material facts concerning the  
12 dangers and risk of injuries associated with the use of CELEBREX including, but not limited to,  
13 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'  
14 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the  
15 serious nature of the risks associated with the use of CELEBREX in order to increase its sales.

16 127. The representations and concealment were undertaken by Defendants with an  
17 intent that doctors and patients, including Plaintiffs, rely upon them.

18 128. Defendants' representations and concealments were undertaken with the intent of  
19 defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and  
20 encourage the sale of CELEBREX.

21 129. Defendants' fraudulent representations evinced their callous, reckless, willful, and  
22 depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

23 130. Plaintiffs' physician and Plaintiffs relied on and were induced by Defendants'  
24 misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX in  
25 selecting CELEBREX treatment.

26 131. Plaintiffs and the treating medical community did not know that the  
27 representations were false and were justified in relying upon Defendants' representations.

28 132. Had Plaintiffs been aware of the increased risk of side effects associated with  
CELEBREX and the relative efficacy of CELEBREX compared with other readily available

1 medications, Plaintiffs would not have taken CELEBREX as he did.

2 133. As a direct and proximate consequence of Defendants' acts, omissions, and  
3 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
4 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
5 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
6 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
7 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
8 preexisting conditions and activation of latent conditions, and other losses and damages.  
9 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
10 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

11 134. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
12 and deliberate disregard for the value of human life and the rights and safety of consumers,  
13 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
14 punish Defendants and deter them from similar conduct in the future.

15 135. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
16 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
17 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

### 18 **SIXTH CLAIM FOR RELIEF**

#### 19 **Unjust Enrichment**

20 136. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
21 fully set forth herein and further allege as follows.

22 137. At all times relevant to this action, Defendants were the manufacturers, sellers,  
23 and/or suppliers of CELEBREX.

24 138. Plaintiffs paid for CELEBREX for the purpose of managing their pain safely and  
25 effectively.

26 139. Defendants have accepted payment from Plaintiffs for the purchase of  
27 CELEBREX.

28 140. Plaintiffs did not receive the safe and effective pharmaceutical product for which  
she paid.



141. It is inequitable and unjust for Defendants to retain this money because Plaintiffs did not in fact receive the product Defendant represented CELEBREX to be.

142. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Damages for loss of consortium, care, comfort, society and companionship in an amount within the jurisdiction of this Court and according to proof;
6. Punitive and exemplary damages;
7. Pre-judgment and post-judgment interest as provided by law;
8. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
9. Such other and further relief as the Court deems just and proper.

Dated: February 13<sup>th</sup>, 2008.

Respectively submitted,

By: Navan Ward Jr.  
Andy D. Birchfield, Jr. (AL State Bar No. BIR006)  
Email: andy.birchfield@beasleyallen.com  
Navan Ward, Jr. (AL State Bar No. WAR062)  
Email: navan.ward@beasleyallen.com  
BEASLEY, ALLEN, CROW, METHVIN,

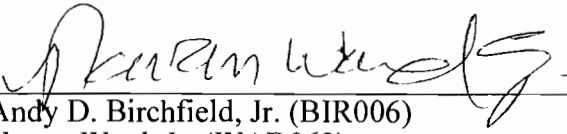
1 PORTIS & MILES, P.C.  
2 Post Office Box 4160  
3 Montgomery, Alabama 36103-4160  
4 (334) 269-2343 telephone  
5 (334) 954-7555 facsimile  
6 Attorneys for Plaintiff

7 **DEMAND FOR JURY TRIAL**

8 Plaintiffs demand a trial by jury on all claims so triable in this action.

9 Dated: February 13<sup>th</sup>, 2008

10 Respectfully submitted,

11 By:   
12

13 Andy D. Birchfield, Jr. (BIR006)  
14 Navan Ward, Jr. (WAR062)  
15 BEASLEY, ALLEN, CROW, METHVIN,  
16 PORTIS & MILES, P.C.  
17 P. O. Box 4160  
18 Montgomery, Alabama 36103-4160  
19 Telephone: (334) 269-2343  
20 Facsimile: (334) 954-7555

21 ATTORNEYS FOR PLAINTIFFS  
22  
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25  
26  
27  
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JS 44 (Rev. 11/04)

## CIVIL COVER SHEET

ADR

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

## I. (a) PLAINTIFFS

OLIVE BEEBE, et al.

## DEFENDANTS

PFIZER, INC., et al.

(b) County of Residence of First Listed Plaintiff Washington, Oregon  
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant New York  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Navan Ward, Jr., Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.,  
P.O. Box 4160, Montgomery, AL 36103-4160; (334) 269-2343

Attorneys (If Known)

E-filing

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff  
☐ 2 U.S. Government Defendant  
☐ 3 Federal Question (U.S. Government Not a Party)  
☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- (For Diversity Cases Only)
- |   |                                       |                                |   |                                |                                       |
|---|---------------------------------------|--------------------------------|---|--------------------------------|---------------------------------------|
| Citizen of This State                   | PTF <input type="checkbox"/> 1        | DEF <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | PTF <input type="checkbox"/> 4 | DEF <input type="checkbox"/> 4        |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2     | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5     | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3     | Foreign Nation  | <input type="checkbox"/> 6     | <input type="checkbox"/> 6            |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition		

## V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding  
☐ 2 Removed from State Court  
☐ 3 Remanded from Appellate Court  
☐ 4 Reinstated or Reopened  
☐ 5 Transferred from another district (specify)  
☐ 6 Multidistrict Litigation  
☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 U.S.C.A. 1332

Brief description of cause:

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

2/13/08

SIGNATURE OF ATTORNEY OF RECORD

Navan Ward Jr.

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_